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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/686,995

Applicant(s)

GERIA, NAVIN

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Request for Continued Examination filed 11/6/06 and the Information Disclosure Statement filed 11/13/06 is acknowledged. Claims 2-5 are pending in this application. Claim 1 is cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/06153 to Moldovanyi in view of Shashkina (4212758).

Moldovanyi teaches soap formulations for the disinfection and cleansing of skin and hands. The formulation comprises (a) 0.01-5% of a microbiocidal active agent of Formulas 1-7; (b) 0.1-25% of one or more hydrotrophic agent; (c) 0-10% surface active agents or a soap; (d) 0-8% of a fatty acid salt; (e) 0-50% dihydric alcohol; (f) 0-70% of a monohydric alcohol; and water to balance with the proviso the composition contains (c) or (d). See abstract and claim 1. The illustrative microbiocidal active agents of formula 3 are benzyl alcohol; 2,4- or 3,5-, or 2,6-dichlorobenzyl alcohol. See page 3. The surface-active agent may be an anionic such as sulfates, alkylamide sulfates, alkylamide ether sulfates, alkylaryl polyether sulfonates, alkylaryl sulfonates, alkane sulfonates, etc. See page 7-8. Alkali metal salts of lauryl ether sulfate are preferred. See page 9. The monohydric alcohol taught is ethanol, propanol, and isopropanol. See page 10.

Specifically example 11 teaches 1 part 2,4-dichlorobenzyl alcohol; 4 parts sodium lauryl sulfate (water-soluble soap); 5 parts sodium cumene sulfonate; 1 part propylene glycol; 8 parts citric acid monohydrate; and water to balance (81%).

Moldovanyi does not teach the use of a propellant.

Shashkina teaches cleansing composition for the skin. The reference teaches the cleansing composition can be conveniently used in aerosol form, which ensures quick formation of homogeneous foam to easily removes solids even from deep folds of the skin without doing any harm to it. An aerosol form is also convenient in transportation and storage and an aerosol forms saves the cleansing agent. Difluorochloromethane may be used as the propellant in a quantity of 10-15%. See column 3, lines 1-10. Shashkina teaches difluorochloromethane promotes formation of fine foam which facilitates the easy and soft distribution of the cleansing agent over the surfaces. See column 5, lines 40-42.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Moldovanyi and Shashkina and further add a propellant to the composition of Moldovanyi. One would have been motivated to do so since Shashkina teaches the advantages of using an aerosol foam to cleanse the skin, including ease is transportation and storage and ease of distribution of the composition over the skin.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/06153 to Moldovanyi in view of Shashkina (4212758) in further view of Lins (5,167,950).

The disclosure of Moldovanyi and Shashkina have been discussed above.

Moldovanyi teaches the use of thickeners on page 11, however the reference does not teach the use of the instant gelling thickeners.

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Lins, while disclosing antimicrobial mousse formulations, teaches the use of thickeners to stabilize the foam and ensure better mixing of the composition with the propellant by preventing crystallization prior to filling in the dispenser. The thickeners include acrylic acid crosslinked with an unsaturated polyfunctional agent, such as polyalkyl ether of sucrose; cellulose ethers such as HPC, HEC, and HMC. See column 5, lines 5-35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and utilize the instant thickener. One would have been motivated to do so with a reasonable expectation of success since WO suggests the use of thickeners in the composition and Lins teaches in the formulation of foams, it advantageous to use polymeric thickeners to provide foam stability. Therefore, it would have been obvious, absent the unexpectedness of using the instant thickener, to use any thickener known to those skilled in the art.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/06153 to Moldovanyi in view of Schraufstatter (2,945,782) in further view of Khan et al (5439681).

Moldovanyi teaches surface-active formulations for the disinfection and cleansing of skin and hands. The formulation comprises (a) 0.01-5% of a microbiocidal active agent of Formulas 1-7 including dichlorobenzyl alcohols and p-chlorophenols; (b) 0.1-25% of one or more hydrotrophic agent; (c) 0-10% surface active agents or a soap; (d) 0-8% of a fatty acid salt; (e) 0-50% dihydric alcohol; (f) 0-70% of a monohydric alcohol; and water to balance. See abstract. The illustrative microbiocidal active agents of formula 3 are benzyl alcohol; 2,4- or 3,5-, or 2,6-dichlorobenzyl alcohol. See page 3. The surface-active agent may be a anionic such as sulfates, alkylamide sulfates, alkylamide ether sulfates, alkylaryl polyether sulfonates, alkylaryl

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sulfonates, alkane sulfonates, etc. See page 7-8. Alkali metal salts of lauryl ether sulfate are preferred. See page 9. The monohydric alcohol taught is ethanol, propanol, and isopropanol (inert volatile liquid). See page 10.

Specifically example 11 teaches 1 part 2,4-dichlorobenzyl alcohol; 4 parts sodium lauryl sulfate (water-soluble soap); 5 parts sodium cumene sulfonate; 1 part propylene glycol; 8 parts citric acid monohydrate; and water to balance (81%). Example 7 uses 12% ethanol with 1% of a microbicidal agent.

Although Moldovanyi teaches the optional use of a monohydric alcohol (ethanol and isopropanol) in the amount of 0-50%, the reference lacks the specific teaching of the monohydric alcohol (ethanol or isopropanol) with the dichlorobenzyl alcohol.

Schraufstatter teaches disinfectant composition comprising dichlorobenzyl alcohol. Schraufstatter teaches the use of alkylsulfates or sulfonates, aralkylsulfonates, alkylarylsulfonate and monovalent or polyvalent alcohols such as ethanol, isopropanol, glycols, and polyglycol are dissolving agents for halogen containing arylalkanols. See column 1, lines 38-45.

Khan teaches an antimicrobial cleansing composition comprising p-chlorophenol. Khan teaches the use of a thickener in an amount of 0.1-1% to increase the viscosity and stability of a formulation. The instant thickeners are taught. See column 7, line 55 to column 8, line 18.

Firstly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Moldovanyi's and Schraufstatter and utilize ethanol or isopropanol, both of which are inert volatile liquids, as the solvent in example 11. One would have been motivated to do so since Schraufstatter teaches that ethanol, isopropanol, or glycols may be used as the solvent for dissolving halogen-containing arylalkanols

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(dichlorobenzyl alcohol). Thus, one would have been motivated to substitute the propylene glycol with as ethanol/isopropanol as the solvent of choice since Schraufstatter teaches that all three are used as solvents for dichlorobenzyl alcohol, i.e. all are functional equivalents in acting as dissolving agents for dichlorobenzyl alcohol. Therefore, a skilled artisan would have expected similar results by utilizing ethanol/isopropanol since the prior art establishes that propylene glycol the solvent used in Moldovanyi and ethanol/isopropanol are functional equivalents.

Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further add a thickener to the composition. One would have been motivated to do so since Moldovanyi suggests the use of thickeners and Khan teaches polymeric thickeners increase viscosity and thus increase stability of the composition. Therefore, it would have been prima facie obvious for a skilled artisan to add a thickener not only to yield the desired viscosity but also to increase the stability of the composition.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens (6,114,396) in view of Tomlinson (4,981,678) in further view of Scholz et al (6,562,360).

Rens teaches a sterilizing or disinfecting composition comprising 2-bromo-2-nitropropan-1,3-diol and 2,4-dichlorobenzyl alcohol. The composition is used as a surgical skin scrub, a sterilizer, and a disinfectant hand spray. See abstract. 2,4-dichlorobenzyl alcohol is taught in an amount of 0.1-10%. See claim 4. The composition further comprises a surfactants such as sodium lauryl sulfate in the amount of 0.1-10%. See column 2, lines 39-45. Rens teaches a surgical hand scrub that contains 2-bromo-2-nitropropan-1,3-diol and 2,4-dichlorobenzyl alcohol and various other additives including thickeners, surfactants, etc. . See column 5, lines 1-5. The

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composition contains 0.1% dichlorobenzyl alcohol, 4% miranol (water-soluble soap), 4% glucamate DOE 120 (water-soluble gelling agent), and water in the instant weight percent.

Rens does not teach an aerosol having a propellant.

Tomlinson teaches a skin disinfectant composition. Tomlinson teaches the composition is in an aerosol form since it is the most appropriate for a biocide since it is easy and safe to use and it avoids or minimizes the conventional defects of contamination and spillage. Further, Tomlinson teaches pressurized aerosol containers are readily available, have been extensively tested and are well accepted. See column 2, lines 40-45.

Scholz teaches a compositions useful as skin disinfectants, surgical hand preparations, patient skin preparations, and antimicrobial hand compositions and the composition is dispensed as a lotion or foam. See abstract and column 1, lines 13-17. The aerosol foam or mousse is formulated by addition of an appropriate propellant. Suitable propellants include chlorofluorocarbons (CFCs), hydrochlorofluorocarbons (HCFCs), hydrofluorocarbons (HFCs), perfluorinated alkanes, and lower alkanes (C1-C5), lower alkanes such as propane, butane, and isobutene. In order to produce an aerosol composition the antimicrobial composition is first formulated and charged into an appropriate pressure rated container. The propellant is then added under pressure at approximately 2-30% preferably 3-20% by volume. The propellant may form a separate layer or may remain emulsified in the composition. see column 21, lines 35-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Rens, Tomlinson, and Scholz, and further utilize an propellant in Rens' composition. One would have been motivated to do so since Tomlinson teaches aerosol foams are the most appropriate form for skin disinfecting composition due to

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several advantages foams present including they are easy and safe to use and avoid problems of spillage and contamination. Further, Tomlinson establishes the state of the art wherein it is known to formulate skin-disinfecting compositions into aerosol form. Scholz teaches propellants are incorporated into skin disinfecting products including surgical scrubs to provide aerosol or a mousse form. Therefore, a skilled artisan would have been motivated to utilize a propellant if one desired to formulate an aerosol product.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rens (6,114,396) in view of Tomlinson (4,981,678) in further view of Scholz et al (6,562,360) in further view of Lins (5,167,950).

The disclosure of Rens, Tomlinson, and Scholz have been discussed above.

Although Rens teaches the use of thickeners, specifically the polymeric thickener Glucamate, the reference does not teach the use of the instant thickener.

Lins, while disclosing antimicrobial mousse formulations, teaches the use of thickeners to stabilize the foam and ensure better mixing of the composition with the propellant by preventing crystallization prior to filling in the dispenser. The thickeners include acrylic acid crosslinked with an unsaturated polyfunctional agent, such as polyalkyl ether of sucrose; cellulose ethers such as HPC, HEC, and HMC. See column 5, lines 5-35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and utilize the instant thickener. One would have been motivated to do so with a reasonable expectation of success since Rens suggest the use of thickeners in the composition and Lins teaches in the formulation of foams, it advantageous to use polymeric thickeners to provide foam stability. Therefore, it would have

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been obvious, absent the unexpectedness of using the instant thickener, to use any thickener known to those skilled in the art.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5,523,081) in view of Buerger et al (5985299) or Korb et al (5,851,543) or Hahn et al (5804203) respectively.

Edwards teaches a cosmetic composition for shaving of the skin comprising from (a) 40-90% by weight of water; (b) from 4-25% by weight of water-soluble soap; (c) from 0.5-12% by weight of an inert volatile liquid agent, (d) optionally from 0.01-5% by weight of water-soluble gelling agent, and (e) 0.01-15% by weight of a polyorganosiloxane micro-emulsion, the micro-emulsion having an average particle size of less than 0.14 microns. See column 2, lines 1-10. Preferred soaps include the water-soluble stearate and palmitates soaps, such as potassium, ammonium, sodium, and the soluble amine soaps of commercial stearate acid and palmitic acid. See column 2, lines 40-55.

Edwards teaches the inert volatile liquid agent used in the aerosol form of the composition should be suitable to function as an aerosol propellant gas and can be selected from a wide variety of the propellants known in the aerosol industry. Suitable inert inorganic gases such carbon dioxide, nitrogen, argon and air. Suitable examples of liquid or liquefied propellant agents include propane, n-butane and iso-butane, or halogenated with fluorine or chlorine, such as monochlorotrifluoromethane, dichlorodifluoromethane, trichloromonofluoromethane, and similar chlorofluorohydrocarbons preferably with from 1 to 3 carbon atoms. See column 3, lines 25-50. Suitable such post-foaming agents for use in the gel compositions are liquids or liquefiable and include saturated aliphatic hydrocarbons having from 4-6 carbon atoms, such as

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butanes, pentanes and hexanes; partially or wholly halogenated hydrocarbons, such as trichlorotrifluoro ethane. See column 4, lines 5-40 and note examples.

The gelling agents used for post-foaming gel type are water-soluble derivatives of naturally occurring substances such as cellulose, sucrose, and glucose. Preferred gelling agents include the co-polymers of acrylic acid and a polyallyl sucrose, and reaction products of cellulose or glucose with acids or alkaline oxides. See column 3, lines 5-25.

Lastly, Edwards teaches the products may additionally comprise other optional ingredients, such as humectant, skin fresheners, lather stabilizers, coloring materials, dyes, perfumes, **preservatives, bactericides, bacteriostats**, and other components routinely used in such compositions. See column 6, lines 25-32.

Edwards does not specify the use of instant dichlorobenzyl alcohol.

Buerger teaches a pore cleaning formulation. Buerger teaches the formulation includes one or more preservatives to stabilize the composition and/or prevent the growth of bacteria, and/or molds. The reference teaches a variety of suitable materials known in the art of cosmetic formulation may be used in this context, for example, methyl paraben, benzalkonium chloride, benzylparaben, **dichlorobenzyl alcohol**, DMDM hydantoin, imidazolidinyl urea, isopropylparaben, quaternium-15, sodium benzoate, etc. The preservative preferably comprises from 0-2% wt of the overall composition on a dry basis, more preferably 0-1% wt, and most preferably around 0.5% wt. See column 6, lines 29-41.

Korb while teaching skin care preparations teaches the composition may include "other agents and ingredients commonly employed" in dermatological and cosmetic compositions such as preservatives such as **dichlorobenzyl alcohol**, benzoic acid, methylparaben and phenyl

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carbinol. See column 7, lines 25-29 and 33-35. The examples utilize the instant weight percent (0.6%) of the preservative.

Hahn while teachings topical composition teaches suitable preservatives include Germaben II, methylparaben, propylparaben, imidazolidinyl urea, benzyl alcohol, sorbic acid, benzoic acid, sodium benzoate, **dichlorobenzyl alcohol**. The examples utilize the preservative in an amount of 0.5-1%. See example 4.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Edwards et al and Buerger; Hahn; or Korb and utilize dichlorobenzyl alcohol as the preservative in Edwards's composition. One would have been motivated to do so with a reasonable expectation of success and results since Edwards suggests utilizing routine adjuvants known in the cosmetic art such as preservatives, stabilizers, etc and Buerger, Korb, and Hahn all teach dichlorobenzyl alcohol is a conventional preservative that "preserves" the composition by reducing the growth of microorganisms in the composition. Therefore, a skilled artisan would have been motivated to utilize a conventional preservative such as instantly claimed dichlorobenzyl alcohol in the composition to extend its shelf life. Furthermore, Buerger, Korb, and Hahn establish the state of the art wherein dichlorobenzyl alcohol is a routine and well known adjuvant (preservative); therefore absent the showing of the unexpectedness of the instant dichlorobenzyl alcohol, it is the examiner's position that it is prima facie obvious to utilize an adjuvant that is conventionally utilized in the cosmetic art.

Response to Arguments

Applicant argues that the primary reference is directed to a shaving product and the secondary reference is directed to a cosmetic pore cleaning composition. It is argued that the

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combination of two different compositions is improper since Buerger's composition is applied, dried, and then peeled off the skin surface. Applicant argues that US '299 does not teach 0.1-5% dichlorobenzyl alcohol for the prevention of bacterial growth on the skin. Applicant argues that '299 teaches dichlorobenzyl alcohol for stabilizing the composition and preventing growth of bacteria and/or molds in the composition. Applicant argues that neither reference suggest the use of dichlorobenzyl alcohol for this purpose.

Applicant's arguments filed 11/6/06 have been fully considered but they are not persuasive. The examiner notes that the two compositions have different intended uses; however the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In instant case, the obviousness rejection is based on the use of dichlorobenzyl alcohol as a preservative in cosmetic compositions. Edwards suggests the use of *routine* adjuvants known in the cosmetic art such as preservatives and stabilizers. Buerger teaches *conventional* preservatives known and used in the cosmetic art include dichlorobenzyl alcohol, to prevent the growth of bacteria and molds in the composition. The fact that the one cosmetic is used for shaving and the other cosmetic is used for cleansing the skin does not change the function of a preservative in the composition. In other words, the intended use of the product is immaterial to the function of a preservative in a composition, i.e. the preservative will "preserve" the cosmetic regardless. Thus, the instant obviousness rejection is not based on the if one would bodily incorporate Buerger's composition into Edward's

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composition, the premise of the rejection is based on the obvious use of dichlorobenzyl alcohol as a preservative. Thus, it is the examiner's position that the combination of Edwards and Buerger renders the instant composition obvious. Applicant has not provided any unexpected results to overcome the rejection based on obviousness.

With regard to applicant's argument that the prior art teaches the use of dichlorobenzyl alcohol for a different purpose, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In instant case, it is noted that Buerger teaches the use of dichlorobenzyl alcohol to stabilize and preserve the composition itself; however the fact that applicant has found that dichlorobenzyl alcohol not only functions as a preservative but also functions to prevent bacteria growth on the skin itself does not provide a patentable distinction.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Sharmila S. Gollamudi
Examiner
Art Unit 1616